24. The apparatus of claim 6, wherein a portion of the device containing radioactive dose means for emitting radiation is expanded in the second position to a deployed configuration positioning the dose means at least partially in contact with the stenosed region of the artery.

25. The apparatus of claim 24, wherein the portion of the device that is expanded includes a balloon with the dose means positioned on the surface of the balloon.

A5

26. The apparatus of claim 24, wherein at least one portion of the device that is expanded includes a stent and the stent includes the dose means.

27. The apparatus of claim 26, wherein the dose means included with the stent is selected from the group consisting of cladding, coating, an additive to the stent material, and attached to the stent.

REMARKS

This application has been reviewed in light of the Office Action mailed April 7, 2000 (hereinafter "Office Action"). Claims 1-5 are allowed by the Office Action. Claims 6-19 are pending in this application with claims 6-19 being rejected by the Office Action. By this amendment, independent Claims 6 and 10 as well as dependent Claims 14 and 16-19 have been amended. New dependent Claims 20-27 have been added. Support for the afore-mentioned amendment is found through this specification and figures. In view of the amendments above and remarks that follow, reconsideration and allowance of this application has been respectfully

requested. The claims have been amended in a manner which is believed to overcome the rejections contained in the Office Action. No new matter or issues are believed to be introduced by this amendment.

CLAIMS REJECTIONS UNDER 35 U.S.C. § 112

Claims 14 -19 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out into and distinctly claim the subject matter which applicant regards as the invention. The Office Action states:

> *In Claim 16, line 3, "perfusion holes" lacks positive antecedent basis. Claim 17 is directed to the intended use of the radioactive dose and fails to further limit the apparatus. In Claims 18-19 the use of "capable of" is indefinite in that it is unclear whether the function is performed or not. Claims 14 and 18-19 appear to add the balloon into the claim, however as discussed in the declaration and looking at the claims this merely appears to be adding back in what was removed from the claims for these new claims, thereby making it unclear how these are not duplicates of the existing independent claims.*

It is respectfully submitted that amended Claims 14 and 16-19 are now in compliance with 35 U.S.C. § 112, second paragraph. Claim 15 depends from amended Claim 14 and is now also believed to be in compliance with 35 U.S.C. § 112. It is respectfully submitted Claims 14-19 are definite and in particular point out and distinctly claim the subject matter which the applicant regards as the invention.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 6-7 stand rejected under 35 U.S.C. § 102 over U.S. Patent No. 4,881,938 to *van't Hooft* (hereinafter "*van't Hooft*"). The Office Action states that Claims 6 and 7 are rejected as being clearly anticipated by *van't Hooft*.

It is respectfully submitted that amended Claim 6 is neither disclosed nor suggested by *van't Hooft*. *van't Hooft* discloses each implant needle is connected to the cart by means of a patient transfer tube having a patient connector and a machine connector connected with a plurality of external tubes, from which cart tubes are selectively inserted into the needle or needles already introduced. The positioning can take place by means of a transport thread movable in the patent transfer tubes and the final position can be detected pneumatically by shutting off an air passage bounded by a shoulder, by means of a control head attached to each tube. See col. 1, lines 23-40; col. 3, line 15 to col. 4, line 33; and FIGS. 1 and 6 below. This structure positions tubes filled with a radioactive material in a final position at which point treatment is performed.

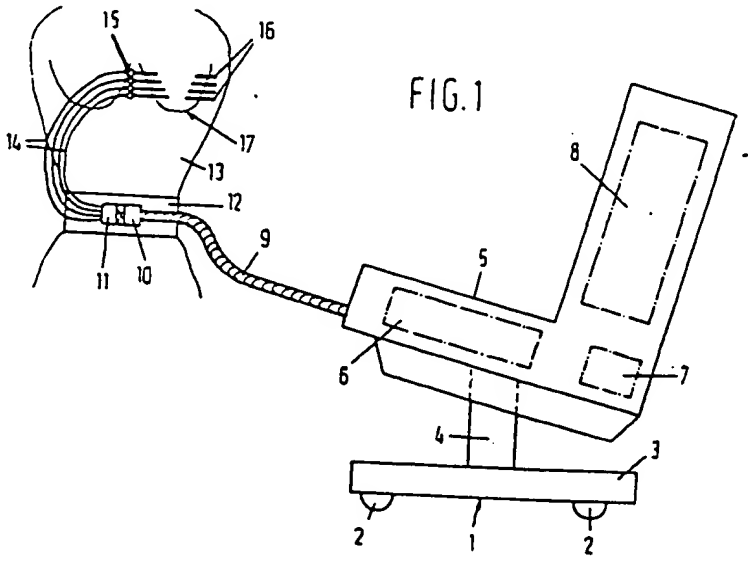
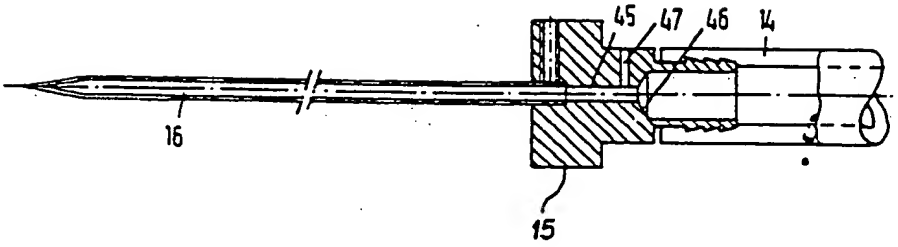


FIG.1

FIG.6



In regard to amended Claim 6, *van't Hooft* fails to teach or suggest, *inter alia*, the newly recited positioning means operatively connected to said device for advancing said device and dose means within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also being operatively connected to said device and dose means for positioning the device and dose means between a first position and a second position, wherein the first position the dose means is positioned within the stenosed region of the artery in a non-deployed configuration and a second position, wherein the dose means is in a deployed configuration for treating at least a portion of the stenosed region of the artery. When positioned, this configuration is used to move from a non-deployed configuration to a deployed treatment configuration in which the patient is being actively exposed to the radiation.

It is respectively submitted that dependent Claim 7 is at least patentable for the reasons that independent Claim 6 from which it directly depends is patentable. Accordingly, withdrawal of this rejection is respectfully requested.

It is respectively submitted that amended Claim 6 is neither disclosed nor suggested by *van't Hooft* and is allowable thereover. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 6-7 and 10-11 stand rejected under 35 U.S.C. § 102 (e) over U.S. Patent No. 5,084,002 by *Liprie* (hereinafter "*Liprie*"). The Office Action states that the above-identified claims were clearly anticipated by *Liprie*.

It is respectfully submitted that amended independent Claims 6 and 10 are neither disclosed nor suggested by *Liprie*. Referring to FIG. 1 of *Liprie*, below, a partial cross-sectional view is shown of a relatively pure iridium core member or seed 12 form in the end of the unitary elongate relatively pure platinum delivery wire 14. See col. 4, lines 18-21 and FIG. 1, below. Thus, the device and the dose means of *Liprie* are fixedly positioned together.

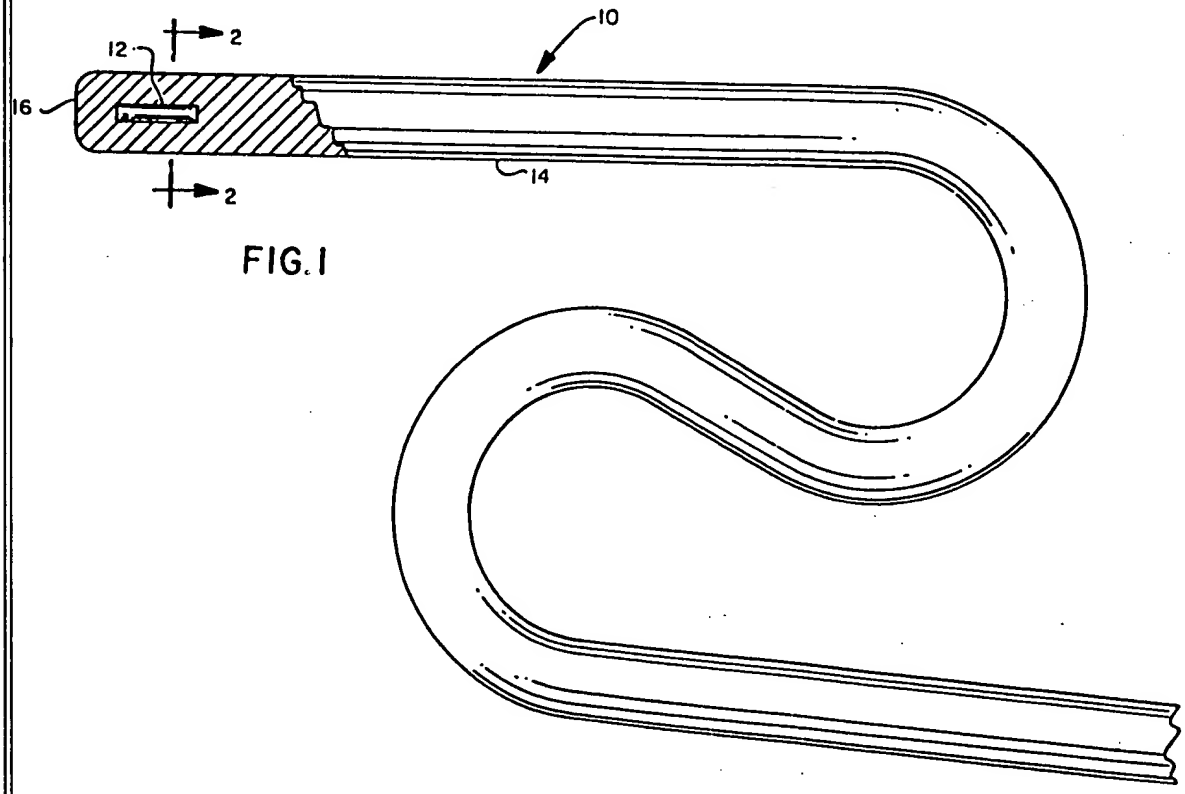


FIG. 1

In regard to amended Claim 6, *Liprie* fails to teach or suggest, *inter alia*, the newly recited positioning means operatively connected to said device for advancing said device and dose means within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also being operatively connected to said device and dose means for positioning the device and dose means between a first position and a second position, wherein the first position the dose means is positioned within the stenosed region of the artery in a non-deployed configuration and a second position, wherein the dose means is in a deployed configuration for treating at least a portion of the stenosed region of the artery. When positioned, this configuration is used to move from a non-deployed configuration to a deployed treatment configuration in which the patient is being actively exposed to the radiation.

It is respectively submitted that dependent Claim 7 is at least patentable for the reasons that independent Claim 6 from which it directly depends is patentable. Accordingly, withdrawal of this rejection is respectfully requested.

It is respectively submitted that amended Claim 6 is neither disclosed or suggested by *Liprie* and is allowable thereover. Accordingly, withdrawal of this rejection is respectfully requested.

In regard to amended independent Claim 10, *Liprie* fails to teach or suggest, *inter alia*, the newly recited catheter having at least one lumen adapted to deliver said radiation source within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said catheter also being adapted to at least partially reposition relative to the radiation source for treatment when positioned within the stenosed region of an artery, the catheter being adapted to at least partially reposition to withdraw said radiation source from the artery after said radiation

source is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region. This configuration is used to control the amount of exposure of the stenosed region of the artery to the radiation and allows movement between two configurations to control that level of exposure.

It is respectfully submitted that dependent Claim 11 is at least patentable for the reasons that independent Claim 10 from which it directly depends is patentable. Accordingly, withdrawal of this rejection is respectfully requested. It is respectfully submitted that amended independent Claims 6 and 10 are neither disclosed nor suggested by *Liprie* and are allowable thereover. Accordingly, withdrawal of this rejection is respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103:

In the Office Action, Claims 8-9 and 12-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Liprie* in view of U.S. Patent No. 3,324,847 by *Zoumboulis* (hereinafter "*Zoumboulis*"). The Office Action states:

> *Claims 8-9, 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie in view of Zoumboulis.*
> *Liprie discloses the claimed device except for the specific use of the radioactive dose in a liquid or gaseous form. Zoumboulis teaches that it is well known to use a radioactive substance in a form other than solid, i.e. liquid. Therefore a modification of Liprie such that the radioactive dose is in any well known and conventionally used form would have been obvious to one skilled in the art.*

It is respectfully submitted that amended independent Claims 6 and 10 are distinguishable and non-obvious when *Liprie* is viewed in light of *Zoumboulis*. For example, in

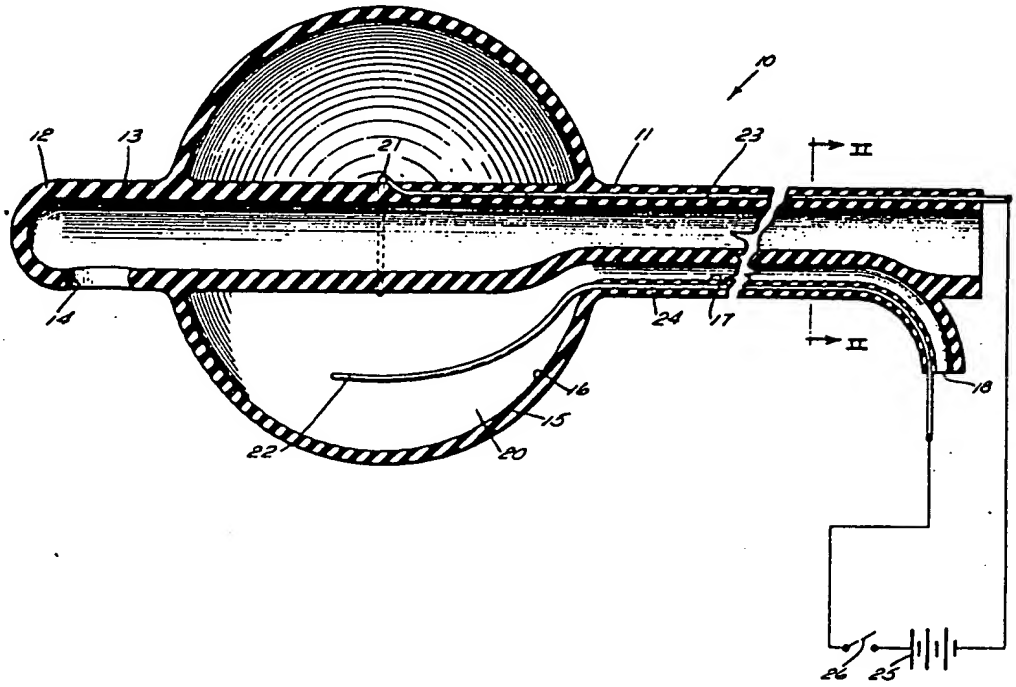
regard to independent Claim 6, the combination of *Liprie* in view of *Zoumboulis* fails to teach or suggest, *inter alia*, applicant's newly recited positioning means operatively connected to said device for advancing said device and dose means within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said positioning means also being operatively connected to said device and dose means for positioning the device and dose means between a first position and a second position, wherein the first position the dose means is positioned within the stenosed region of the artery in a non-deployed configuration and a second position, wherein the dose means is in a deployed configuration for treating at least a portion of the stenosed region of the artery. When positioned, this configuration is used to move from a non-deployed configuration to a deployed treatment configuration in which the patient is being actively exposed to the radiation.

In amended independent Claim 10, the combination of *Liprie* in view of *Zoumboulis* fails to teach or suggest, inter alia, applicant's newly recited a catheter having at least one lumen adapted to deliver said radiation source within the stenosed region of an artery that has been reduced by angioplasty or other procedure, said catheter also being adapted to at least partially reposition relative to the radiation source for treatment when positioned within the stenosed region of an artery, the catheter being adapted to at least partially reposition to withdraw said radiation source from the artery after said radiation source is exposed to the stenosed region for a period of time sufficient to reduce restenosis of the stenosed region.

In contrast, *Liprie* teaches a source 10 that includes a relatively pure iridium core member or seed 12 formed in the end of a unitary elongated pure platinum delivery wire 14. See col. 4, lines 16-21 and FIG. 1, above. *Zoumboulis* discloses the use of electrodes in combination

with this solution containing a radioactive isotope that is particularly advantageous in that ions are formed in the solution and migrate to one of the electrodes in acceptance with laws of iontophoresis to accumulate a solid radioactive source. See col.1, lines 20-48 and FIG. 1, below.

Fig. 1



Thus, neither *Liprie* nor *Zoumboulis* teach or suggest, *inter alia,* positioning means operatively connected to said device that is movable when positioned between a first non-deployed configuration and a second deployed configuration. Further, neither *Liprie* nor *Zoumboulis* teach or suggest, *inter alia,* an arrangement where a catheter is adapted to at least partially reposition relative to the radiation source for treatment. Accordingly, withdrawal of this rejection is respectfully requested.

It is respectfully submitted that amended independent Claims 6 and 10 are patentably distinguishable when *Liprie* is reviewed in light of *Zoumboulis* and therefore allowable thereover. It is respectfully submitted that dependent Claims 8-9 and 12-13 are at least patentably

distinguishable for the reason amended independent Claims 6 and 10 from which they respectively depend are patentable. Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

It is respectfully submitted that none of the references of record disclose or suggest the present invention is claimed in the claims as amended considered or in combination with themselves considered in whole or in part. Accordingly, withdrawal of this rejection is respectfully requested. In view of the foregoing amendments and remarks, reconsideration of the rejections and allowance of the claims are earnestly solicited.

Respectfully submitted,

David M. Carter

David M. Carter
Registration No. 30, 949
Attorney for Applicant

DILWORTH & BARRESE, LLP
333 Earle Ovington Boulevard
Uniondale, New York 11553
(516) 228-8484